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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/567,150

10/02/2006

Tetsuya Ikemoto

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FOLEY AND LARDNER LLP  
SUITE 500  
3000 K STREET NW  
WASHINGTON, DC 20007

EXAMINER

KEYS, ROSALYND ANN

ART UNIT

PAPER NUMBER

1621

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/567,150	<b>Applicant(s)</b> IKEMOTO ET AL.	
	<b>Examiner</b> ROSALYND KEYS	<b>Art Unit</b> 1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 04 August 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Status of Claims***

1. Claims 1-15 are pending.

Claims 1-15 are rejected.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 14 and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not provide support for the reagent comprising a mild acid.

### ***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 6-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Gu (J. Org. Chem., Vol. 51, No. 26, December 1986, pp. 5425-5427).

Gu et al. teach a compound having the claimed formula (I), see compound 2, right column of page 5425.

### ***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gu et al. (J. Org. Chem., Vol. 51, No. 26, December 1986, pp. 5425-5427) in view Beauchamp et al. (J. Med. Chem., Vol. 31, No. 1, January 1988, pp. 144-149) and further in view of Horino et al. (US 5,739,100).

Gu et al. teach a compound having the claimed formula (I) and a process of preparing said compound by reacting a compound having the claimed formula (V) in the presence of a base, such as sodium hydroxide (see reaction Scheme II on page 5425 and the General Procedure, right column on page 5426). Gu et al. inherently teach the claimed method of protecting a hydroxyl group, since Gu et al. teach reacting a hydroxyl group-containing compound with a compound having the claimed formula (I) in the presence of an acid (see page 5425 right column thru to the General Procedure, right column on page 5426, in particular the left column on page 5426).

Gu et al. differ from the instant claims in that they obtain their starting compound having the claimed formula (V) by a different method.

Beauchamp et al. teach a method of preparing the compound having the claimed formula (V) by reaction of a compound having the claimed formula (III) with a compound having the claimed formula (IV), see preparation method for compound (3), left column of page 147.

One having ordinary skill in the art the time the invention was made would have found it obvious to utilize any known method of obtaining the starting material of Gu et al., including the method of Beauchamp et al., with a reasonable expectation of success. The claim would have been obvious because “a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense.” KSR International Co. v. Teleflex Inc., 550 U.S.\_\_\_\_, 82 USPQ2d 1385, 1395-97 (2007).

Gu et al. in view of Horino et al. further differ from claims 10 and 12 in that X for Gu et al. and Horino et al. is Cl, whereas amended claims 10 and 12 now require X to be F, Br, or I.

However, since Cl, F, Br and I are all halogens and therefore analogous, the ordinary skilled artisan would reasonably expect the reactions of claims 10 and 12 to proceed similarly to those disclosed by Gu et al. in view of Horino et al.

Gu et al. further differs from the instant claims when the acid catalyst is pyridinium p-toluenesulfonate or p-toluenesulfonic acid.

Horino et al. teach that pyridinium p-toluenesulfonate and p-toluenesulfonic acid are conventional acid catalysts (see column 4, lines 25-37).

One having ordinary skill in the art at the time the invention was made would have found it obvious to utilize any known acid catalyst in place of the sulfuric acid disclosed by Gu et al., including any of the conventional acid catalysts disclosed by Horino et al. with a reasonable expectation of success. Further, the selection of a

known material based on its suitability for its intended use supported a prima facie obviousness determination in *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945).

### ***Response to Arguments***

*Rejection of claims 6-9 under 35 U.S.C. 102(b) as being anticipated by Gu et al. (J. Org. Chem., Vol. 51, No. 26, December 1986, pp. 5425-5427)*

10. Applicant's arguments filed August 4, 2008 have been fully considered but they are not persuasive.

The Applicants argue that Gu fails to teach a hydroxyl-protecting group represented by formula (II), as recited in amended claim 6.

This argument is not persuasive because this amendment is directed to the intended use of the compound of formula (I) and is therefore not a limitation. The structure of the instant compound is not distinguishable from the structure of the compound disclosed by Gu. Thus, claims 6-9 are anticipated by Gu.

For the above reasons, this rejection is maintained.

*Rejection of claims 1-13 under 35 U.S.C. 103(a) as being unpatentable over Gu et al. (J. Org. Chem., Vol. 51, No. 26, December 1986, pp. 5425-5427) in view Beauchamp et al. (J. Med. Chem., Vol. 31, No. 1, January 1988, pp. 144-149) and further in view of Horino et al. (US 5,739,100)*

11. Applicant's arguments filed August 4, 2008 have been fully considered but they are not persuasive.

A. *The Rejection of claims 1-5*

The Applicants argue that In contrast to Applicants' invention as defined by claim 1, Gu et al. teach reacting 2-(chloromethyl)-3,5-dioxahex-1-ene with alcohol by multiple steps (1) under basic condition, and (2) acidic condition, to form acetylated alcohols. Such compounds clearly do not comprise a protecting group represented by Applicants' formula (II).

This argument is not persuasive because claim 1 uses the transitional term "comprising" which is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. Thus, Gu et al. use of multiple steps (1) under basic condition, and (2) acidic condition is not excluded from the instant claims. With respect to the acetylated alcohols formed in Gu et al., the claims disclose that for formula (II) R can be an optionally substituted alkyl group. Thus, the acetylated alcohol of Gu et al. ( $-\text{CH}_2\text{OCH}_2\text{C}(\text{O})\text{CH}_3$ ) meets the claimed definition for the protecting group having formula (II) ( $-\text{CH}_2\text{OR}$ ).

B. *The Rejection of claim 6-9 and new claims 14-15*

The arguments with respect to claims 6-9 are not persuasive for the same reasons given above in paragraph 10.

With respect to claims 14 and 15, Horino et al. teach that pyridinium p-toluenesulfonate and p-toluenesulfonic acid are conventional acid catalysts. Thus, when these catalysts are substituted for the sulfuric acid of Gu et al., then the crude



reagent will contain some of the catalyst. Thus, new claims 14 and 15 will be met by the combination of Gu et al. and Horino et al.

With respect to claims 10 and 12, since all of the substituents are halogens and therefore analogous, the skilled artisan would reasonably expect the reactions of claims 10 and 12 to proceed similarly to those disclosed by Gu et al. in view of Horino et al.

For the above reasons, the Examiner believes that the instant claims 1-15 are unpatentable over Gu et al. (J. Org. Chem., Vol. 51, No. 26, December 1986, pp. 5425-5427) in view of Beauchamp et al. (J. Med. Chem., Vol. 31, No. 1, January 1988, pp. 144-149) and further in view of Horino et al. (US 5,739,100).

### ***Conclusion***

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

Art Unit: 1621

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROSALYND KEYS whose telephone number is (571)272-0639. The examiner can normally be reached on M, W, F 8 am-3:30 pm; T, Th 5:30 am-7 am & 9:30 am-5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel Sullivan can be reached on 571-272-0779. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ROSALYND KEYS/  
Primary Examiner, Art Unit 1621

October 25, 2008

Application/Control Number: 10/567,150  
Art Unit: 1621

Page 10